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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/628,803      | 07/28/2000  | John J. Murphy       | 112910.3302         | 3501             |

7590 07/30/2002

Pepper Hamilton LLP  
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Washington, DC 20005-2004

EXAMINER

HUI, SAN MING R

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1617

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/628,803

Applicant(s)

MURPHY ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 28, 2002 has been entered.

The Notice of Appeal filed January 18, 2002 is acknowledged.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doble et al. (J Pharmacol Exp Ther 266(3):1213-26 from the Information Disclosure Statement received March 14, 2001) in view of Novo Nordisk (English abstract of Denmark Patent DK9800727 from the Information Disclosure Statement received March 14, 2001) and Sandyk (International Journal of Neuroscience, 1995, 83(1-2): 81-92), references of record in the final office action mailed September 25, 2001.

Doble et al. teaches that pagoclone is a partial agonist of GABA<sub>A</sub> receptor (see page 1224, col.2, first paragraph and page 1225, first col., last paragraph).

However, Doble et al. does not expressly teach the administration of pagoclone in methods of treating stuttering.

Novo Nordisk teaches that stuttering is a disorder which is related to GABA-uptake activity (See abstract).

Sandyk teaches that the immediate improvement of dysarthria stuttering is the result of changes in the synthesis and release of GABA (See page 81, the abstract). Sandyk also teaches that cerebellar GABA deficiency contributes to the development of dysarthria (See page 87, second paragraph; page 88, fourth paragraph).

Therefore it would have been obvious for one of ordinary skill in the art at the time the invention was made to administer pagoclone to a patient in a method to treat stuttering.

One of ordinary skill in the art would have been motivated to administer pagoclone in a method to treat stuttering because the decrease of GABA neurotransmission is known to be associated with the development of dysarthria and stuttering in the prior art. Therefore administering to patients suffering from stuttering any known partial agonist of GABA<sub>A</sub> including the elected compound, known to increase the GABA activity, would be expected to produce beneficial effects in the treatment of a patient suffering from stuttering or dysarthria.

### ***Response to Arguments***

Applicant's arguments filed May 28, 2002 averring the cited prior art's failure to suggest employing pagoclone to treat stuttering have been fully considered but they are not persuasive. Novo Nordisk and Sandyk teaches that GABA functions are associated with the development of stuttering. Possessing the teaching of Sandyk, i.e., the immediate improvement of stuttering was observed with increasing GABA neurotransmitter function, one of ordinary skill in the art would reasonably expect any ligand having agonistic properties at the GABA receptor to bind to the GABA receptor, including an agonist (GABA itself) or a partial agonist (pagoclone), to increase GABA neurotransmitter function and activities and be useful in improving or treating stuttering, absent evidence to the contrary.

Applicant's arguments filed May 28, 2002 averring the cited prior arts provide no reasonable expectation have been fully considered but they are not persuasive. As discussed above, possessing the teaching of Sandyk, one of ordinary skill in the art would reasonably expect any ligand having agonistic properties at the GABA receptor to bind to the GABA receptor, including an agonist (GABA itself) or a partial agonist (pagoclone), to increase GABA neurotransmitter function and activities and be useful in improving or treating stuttering since immediate improvement of stuttering is observed with increasing GABA neurotransmitter function.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-

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1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
July 29, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200